

INITIAL BATCH RECORD

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APPENDIX G

Site: Administration of Porcine Spinal Cord Cells (SCIR)
Document Number: BR0055-0

Revision: 00
Effective Date APR 12 2001

Patient Number SRL-05 Sex: M Age: 38 Treatment: Spinal Cord Cells
Target site/spinal segment(s) T5-T6 Length of spinal segment(s) 2cm
Number of Targets planned: 10 Injury Location T5-6
Product Lot Number: SCIR009 Date: 4/25/01

Injection Site Location	Left Targets	Right Targets
Injection Site 1 5 5 5 5	Start Time <u>4:33</u> Stop Time <u>4:40</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T5</u>	Start Time <u>5:10</u> Stop Time <u>5:14</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T6</u> 6 5 5 5 5
Injection Site 2 5 5 5 5	Start Time <u>4:45</u> Stop Time <u>4:50</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T5</u>	Start Time <u>5:15</u> Stop Time <u>5:19</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T6</u> 7 5 5 5 5
Injection Site 3 5 5 5 5	Start Time <u>4:51</u> Stop Time <u>4:55</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T5</u>	Start Time <u>5:20</u> Stop Time <u>5:25</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T5</u> 8 5 5 5 5
Injection Site 4 5 5 5 5	Start Time <u>4:59</u> Stop Time <u>5:04</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T6</u>	Start Time <u>5:25</u> Stop Time <u>5:30</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T5</u> 9 5 5 5 5
Total Volume		

Comments (Please comment on deviations, i.e., unable to equalize space injections, less than 10 μ l per injection administered.)

5:05 start
5:09 stop
20 μ l vol
T6 segment

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Indicate order numerically of cell deposits.

Anterior	
R	L
o <u>1</u>	o <u>9</u>
o <u>2</u>	o <u>8</u>
o <u>3</u>	o <u>7</u>
o <u>4</u>	o <u>6</u>
5	
Posterior	

Signature of Recording Operator:

Jonathan Dinsmore

Date

9/25/01

injections into and below injury.

JHD 9/26/01

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Patient Number: LDS-04 Sex: M Age: 21 Treatment: Spinal Cord Cells
Target site/spinal segment(s): T10-12 Length of spinal segment(s):
Number of Targets planned: 10 Injury Location: T10-11
Product Lot Number: SCIR 008 Date: 7/10/01

Injection Site Location	Left Targets	Right Targets
Injection Site 1 L 5 5 5 5	Start Time <u>11:24</u> Stop Time <u>11:27</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T10</u>	Start Time <u>11:44</u> Stop Time <u>11:48</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T12</u>
Injection Site 2 R 5 5 5 5	Start Time <u>11:29</u> Stop Time <u>11:32</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T10</u>	Start Time <u>11:49</u> Stop Time <u>11:53</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T12</u>
Injection Site 3 L 5 5 5 5	Start Time <u>11:34</u> Stop Time <u>11:38</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T10</u>	Start Time <u>11:54</u> Stop Time <u>11:57</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T12</u>
Injection Site 4 R 5 5 5 5	Start Time <u>11:39</u> Stop Time <u>11:43</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T10</u>	Start Time <u>11:58</u> Stop Time <u>12:02</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>T12</u>
Total Volume		

Comments (Please comment on deviations, i.e., unable to equally space injections, less than 10 μ l per injection administered.)

Start 12:03
Stop 12:06

vol. 20

start 12:06
stop 12:09

vol

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APR 12 2001

1. Indicate order numerically of cell deposits.

L	Anterior	R
o <u>1</u>		o <u>2</u>
o <u>3</u>		o <u>4</u>
o <u>9</u>		o <u>10</u>
o <u>5</u>		o <u>6</u>
<u>7</u>		<u>8</u>
Posterior		

Signature of Recording Operator:

Jonathan Derosiere

Date

7/10/01

per protocol $\leq 30 \times 10^6$ cells

per protocol inject above, below and at injury site

T10 above

T11 at

T12 below

per protocol from 1-4 injection sites/side

per protocol all injections within one segment

JHD 7/31/01

Patient Number WDS-03 Sex: M Age: 27 Treatment: Spinal Cord Cells
Target site/spinal segment(s) C6 #7/10/11 Length of spinal segment(s) _____
Number of Targets planned: 5 Injury Location C7
Product Lot Number: SCIR 007 Date: 10/12/01

Injection Site Location	Left Targets # 6/12/01	Right Targets # 6/12/01
Injection Site 1 9:41 9:41 54 ✓ 5 ✓ 5 ✓ 5 ✓ 2 ✓	Start Time <u>9:40</u> Stop Time <u>9:45:15</u> ; 9:46:45 (1) Injection Volume: <u>22</u> µl Approximate Spinal Cord Segment: _____	Start Time <u>10:12:10</u> RESTART <u>10:15:00</u> (5) Stop Time _____ Injection Volume: <u>23</u> µl Approximate <u>NOT INJECTED</u> Spinal Cord Segment: _____
Injection Site 2	Start Time <u>9:49:20</u> Stop Time <u>9:54:15</u> (2) Injection Volume: <u>20</u> µl Approximate Spinal Cord Segment: _____	Start Time <u>10:17:30</u> Stop Time <u>10:22:30</u> (6) Injection Volume: <u>23</u> µl Approximate Spinal Cord Segment: _____
Injection Site 3	Start Time <u>9:56:40</u> Stop Time <u>10:01:40</u> (3) Injection Volume: <u>20</u> µl Approximate Spinal Cord Segment: _____	Start Time _____ Stop Time _____ Injection Volume: _____ µl Approximate Spinal Cord Segment: _____
Injection Site 4	Start Time <u>10:04:12</u> Stop Time <u>10:09:12</u> (4) Injection Volume: <u>23</u> µl Approximate Spinal Cord Segment: _____	Start Time _____ Stop Time _____ Injection Volume: _____ µl Approximate Spinal Cord Segment: _____
Total Volume		

removed 15 sec.
HR 41
54/min
injected
HR 58
@ 10:15
47, out
@ 10:15:10
HR 58
@ 10:17

Comments (Please comment on deviations, i.e., unable to equally pace injections, less than 10 µl per injection administered.)

Dr. Diksis stated he injected very slowly over each 5-minute injection time, "practically"

Target 5 not injected: syringe inserted twice, but heart rate dropped both times. Moved to site #6, with full syringe (23 µl); site 6 injected without difficulty.

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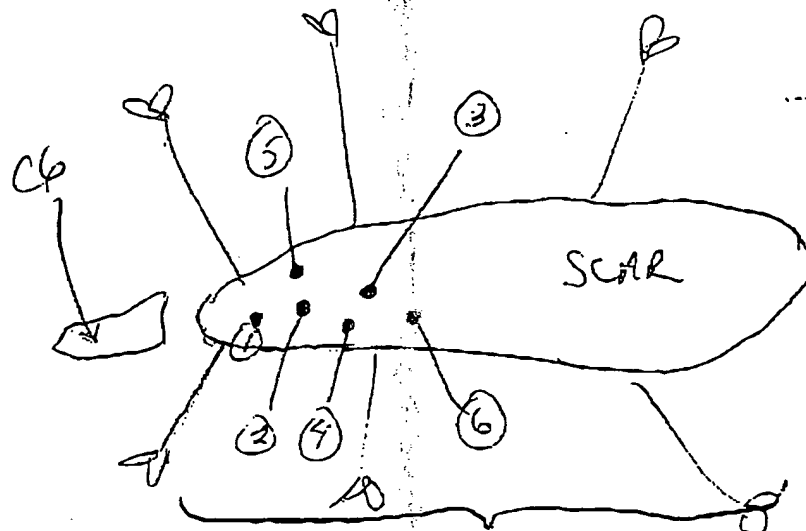
APR 12 2001

Indicate order numerically of cell deposits.

Anterior	
O__	O__
O__	O__
O__	O__
O__	O__
Posterior	

Signature of Recording Operator: AEKDate recorded 6/12/01
" signed 7/9/01

all into "column level superior C7"



C6-C7
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Title: Administration of Porcine Spinal Cord Cells (SCIR)
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Patient Number: 240-02 Sex: F Age: 56 Treatment: Spinal Cord Cells
Target site/spinal segment(s): T12-L1 Length of spinal segment(s):
Number of Targets planned: JD 7/5/01 Injury Location: T12 JD 7/5/01
Product Lot Number: SCIR 006 Date: 5/16/01

Injection Site Location	Left Targets	Right Targets
Injection Site 1 111 T12 JD 7/5/01	Start Time <u>9:15 PM</u> Stop Time <u>9:25</u> Injection Volume: <u>20</u> μ l Approximate <u>T12 JD 7/5/01</u> Spinal Cord Segment: <u>T12</u>	Start Time <u>10:00</u> Stop Time <u>10:05</u> 111 Injection Volume: <u>20</u> μ l Approximate <u>T JD 7/5/01</u> Spinal Cord Segment: <u>T11</u>
Injection Site 2 1111 T12 JD 7/5/01	Start Time <u>9:30 PM</u> Stop Time <u>9:35</u> Injection Volume: <u>20</u> μ l Approximate <u>T12</u> Spinal Cord Segment: <u>T12</u>	Start Time <u>10:02</u> Stop Time <u>10:10</u> 111 Injection Volume: <u>20</u> μ l Approximate <u>T JD 7/5/01</u> Spinal Cord Segment: <u>T11</u>
Injection Site 3 111	Start Time <u>9:50</u> Stop Time <u>9:53</u> Injection Volume: <u>20</u> μ l Approximate <u>T JD 7/5/01</u> Spinal Cord Segment: <u>T11</u>	Start Time <u>10:15</u> Stop Time <u>10:19</u> 111 Injection Volume: <u>20</u> μ l Approximate <u>T JD 7/5/01</u> Spinal Cord Segment: <u>T12</u>
Injection Site 4 1111	Start Time <u>9:55</u> Stop Time <u>9:58</u> Injection Volume: <u>20</u> μ l Approximate <u>T JD 7/5/01</u> Spinal Cord Segment: <u>T11 JD 7/5/01</u>	Start Time <u>10:24</u> 111 Stop Time <u>10:25</u> Injection Volume: <u>20</u> μ l Approximate <u>T JD 7/5/01</u> Spinal Cord Segment: <u>T12 JD 7/5/01</u>
Total Volume		

Comments (Please comment on deviations, i.e., unable to equally space injections, less than 10 μ l per injection administered.)

Cells placed above and at injury site. Because
injury is due to demyelination. Transplant at the site of
injury is warranted.
JD 2/2/02

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Anterior	
o <u>5</u>	o <u>4</u>
o <u>6</u>	o <u>3</u>
o <u>7</u>	o <u>2</u>
o <u>18</u>	o <u>1</u>
Posterior	

Signature of Recording Operator:

Jonathan Quisenberry

Date

*Recorded 5/16/01 +
signed 7/5/01*

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ent Number CCD-01 Sex: M Age: 50 Treatment: Spinal Cord Cells
get site/spinal segment(s) C5-C6 Length of spinal segment(s) _____
nber of Targets planned: 6 Injury Location C6-C8
duct Lot Number: SCIR005 Date: 4-13-01

Injection Site	Left Targets	Right Targets
Injection Site 1	Start Time <u>10:14</u> Stop Time <u>11:20</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>C5</u>	Start Time <u>10:44</u> midline posterior Stop Time <u>10:51</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>C5</u>
Injection Site 2	Start Time <u>11:22</u> Stop Time <u>11:29</u> Injection Volume: <u>21</u> μ l Approximate Spinal Cord Segment: <u>C5</u>	Start Time <u>10:55</u> slightly lateral to midline first injection Stop Time <u>11:02</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>C5</u>
Injection Site 3	Start Time <u>11:31</u> midline slightly to right Stop Time <u>11:38</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>C5</u>	Start Time <u>11:05</u> Stop Time <u>11:12</u> Injection Volume: <u>20</u> μ l Approximate Spinal Cord Segment: <u>C5</u>
Injection Site 4	Start Time <u>11:41</u> Stop Time <u>11:48</u> Injection Volume: <u>21</u> μ l Approximate Spinal Cord Segment: <u>C5</u>	Start Time _____ Stop Time _____ Injection Volume: _____ μ l Approximate Spinal Cord Segment: _____
Total Volume		

omments (Please comment on deviations, i.e., unable to equally space injections, less than 10 μ l per injection administered.)

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Indicate order numerically of cell deposits.

Anterior	
O <u>4</u>	O <u>1</u>
O <u>5</u>	O <u>2</u>
O <u>6</u>	O <u>3</u>
O <u>7</u>	O <u> </u>
Posterior	

C 4

C 6 - 7

Signature of Recording Operator: InjuryDate 4-13-01

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